K070876

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
Stryker® Twist Drills

APR 27 2007

General Information

Proprietary Name:	Stryker® Twist Drills
Common Name:	Drills, Burrs, Trephines, and Accessories
Proposed Regulatory Class:	Class II
Device Classification:	HBE (21 CFR 882.4310) Powered simple cranial drills, burrs, trephines, and their accessories
Submitter:	Stryker® Craniomaxillofacial 750 Trade Centre Way Suite 200 Kalamazoo, MI 49002 877-534-2464 x 4250
Submitter's Registration #:	3005101424
Manufacturer's Registration #:	8010177
Contact Person:	Tennille Folk Regulatory Affairs Representative Phone: 877-534-2464 x 4250 Fax: 269-323-4215
Summary Preparation Date:	March 13, 2007

Intended Use

The Stryker® Twist Drills are intended to be used for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.

Substantial Equivalency Information

Stryker® considers the Stryker® Twist Drills equivalent to the existing Twist drills which are classified as class I devices. Stryker® Twist Drills are also equivalent to Stryker 75K Straight Drill K943541, Stryker Oral Max System K954690 and Lorenz Twist Drills K062842.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Craniomaxillofacial
% Ms. Tennille Folk
Regulatory Affairs Representative
750 Trade Centre Way, Suite 200
Portage, Michigan 49002

APR 27 2007

Re: K070876
Trade/Device Name: Stryker® Twist Drills
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories
Regulatory Class: II
Product Code: HBE
Dated: April 12, 2007
Received: April 17, 2007

Dear Ms. Folk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K

Device Name: *Stryker® Twist Drills*

Indications for Use:

The Stryker® Twist Drills are intended to be used for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.

Prescription Use_____X_____ AND/OR Over-the-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070876

Page __ of ___